POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M82-5 (rev.) 29 October 1999

MANUAL TRANSMITTAL SHEET

SUBJECT: The Use of Foreign Drugs (Unlicensed in the U.S.A.) Brought into the Clinical Center by Patients for Therapeutic and Not Research Use

1. Explanation of Material Transmitted: This issuance sets forth the Clinical Center's policy on the use of foreign drugs (unlicensed in the United States) that are brought into the Clinical Center for therapeutic and not research use. The policy defines the conditions under which such drugs may be used in the Clinical Center, provides that these drug products will not be registered as investigational drugs, and is intended to safeguard nursing staff should they be asked to administer medications that do not have a Pharmacy Department label on them. The policy was reviewed by the Medical Executive Committee on 19 October 1999 and approved with a minor change.

2. Material Superseded: MAS M82-5 (rev.), dated 20 May 1997

3. Filing Instructions: Pharmacy Section

   Remove: No. M82-5 (rev.), dated 20 May 1997

   Insert: No. M82-5 (rev.), dated 29 October 1999

DISTRIBUTION

Physicians, Dentists, and Other Practitioners Participating in Patient Care

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M82-5 (rev.) 29 October 1999

SUBJECT: The Use of Foreign Drugs (Unlicensed in the U.S.A.)
Brought into the Clinical Center by Patients
for Therapeutic and Not Research Purposes

PURPOSE

This issuance sets forth the Clinical Center's policy on the use of foreign drugs (unlicensed in the United States) that are brought into the Clinical Center by patients for therapeutic and not research use. The policy defines the conditions under which such drug products may be used in the Clinical Center.

POLICY

Following are the conditions governing the use of foreign medications (unlicensed in the United States) that are brought into the Clinical Center by patients for therapeutic and not research use:

1. The patient must have been maintained effectively on the drug in his/her country, where the drug was available commercially and used therapeutically.

2. The attending (admitting) physician must be willing to assume responsibility for the prescribing and administration of the drug.

   Unless the drug can be identified and assayed prior to use, its purity and identity cannot be assured. It is incumbent upon the physician to obtain as much information as possible about the drug product and manufacturer prior to its use.

3. Before the drug is used, the attending physician must obtain approval (verbal or written) from his/her Branch Chief and Clinical Director. If approval is obtained verbally, the attending physician must submit a memorandum to the Clinical Director or his/her designee indicating the specific circumstances under which the drug will be used, as agreed upon. Approval must depend on: the attending physician's familiarity with the drug, its use, properties, and manufacturer, the importance of/need for continuing the drug treatment, and the drug being labeled and identified.

4. The physician should document in the progress notes of the patient's medical record that he/she advised the patient that the drug has not been approved by the Food and Drug Administration (FDA); the limits of the Clinical Center's knowledge about the safety and effectiveness of the medication in general, and the identity and purity of the patient's supply in particular; and, the inability of the Clinical Center to refill the prescription once the patient's supply is expended. If the patient indicates that he/she intends to continue using the drug, this also should be recorded.

5. The Pharmacy Department will register the drug and affix an auxiliary label to it bearing the words:

"Pharmacy Department"
PDS control number
Source: Patient's name
Status: Unverified drug

The drug product will not be relabeled, nor will it be registered as an investigational drug.

Although the Pharmacy Department may have registered the drug and affixed an auxiliary label to it, this does not assure the drug's identity and purity. Such assurance can be provided only if the Pharmacy Department has been given sufficient time to identify and assay the drug product.